

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

1 M

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/7484, 542 | 06/07/95 | BRADER | M X-10097 |

| | | | |
|--------------------------|-----------|--------------------------|----------|
| <input type="checkbox"/> | HM12/0413 | <input type="checkbox"/> | EXAMINER |
|--------------------------|-----------|--------------------------|----------|

BANNER & ALLEGRETTI LTD
ELEVENTH FLOOR
1001 G STREET NW
WASHINGTON DC 20001-4597

ALLEN, M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631 | 21 |

DATE MAILED: 04/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|--------------------------------------|-----------------------------------|
| Application No. 08/484,542 | Applicant Brader et al. |
| Examiner Marianne P. Allen | Group Art Unit 1631 |

- Responsive to communication(s) filed on _____
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 835 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 27-35 and 56 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 27-35 and 56 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1631

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1630, Art Unit 1631.

The request filed on 12/17/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/484,542 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 25-26 and 36-55 have been cancelled. Claim 56 has been newly introduced. Claims 27-35 and 56 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is confusing in reciting "further comprising" as claim 28 already possesses a limitation to zinc and claim 29 merely adds a limitation to the amount present.

Claim 31 is confusing in reciting "5 mg of per milliliter." It appears that a word is missing.

Art Unit: 1631

Claims 27-35 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by either of Havelund et al. (U.S. Patent No. 5,750,497) or Havelund et al. (U.S. Patent No. 6,011,007).

This rejection is maintained for reasons of record for the '497 patent as applied to claims 27-35 in the prior Office action and newly applied to claim 56 for the same reason. It is noted that the '007 patent is a continuation-in-part of the '497 patent and that both sets of claims are directed to overlapping subject matter that anticipates the instant claims.

Applicant is reminded that a 1.131 declaration is not proper where the prior art is a patent claiming the same invention as applicant. If the effective filing date of the application is more than 3 months after the effective filing date of the patented application, the applicant must comply with 1.608(b). See MPEP 2306-2307 and 2308.01-2308.02.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Baker et al. (U.S. Patent No. 5,922,675) is cited as being of interest.

It is noted that the invention claimed in the '675 patent is not the same as the present claimed invention as the examiner again notes applicant's previous argument that the instant specification narrowly defines "insulin" to be directed to normal or naturally occurring insulin from beef, pork, and human and does not encompass acylated analogs and that the teachings and claims of the '675 patent are directed to acylated analogs and not acylated normal or naturally occurring insulin from beef, pork, and human. Furthermore, the previously submitted 1.131

Art Unit: 1631

declaration by Brader and Beckage (Paper No. 15) is permissible to remove this reference as the '675 patent disclosure is identical to Baker et al. (U.S. Patent No. 5,793,609) and the claims have not been substantively amended. (See prior Office action.) Likewise, a double patenting rejection does not appear to be merited at this time when the instant claims and '675 claims are compared as the claims of the '675 patent are directed to compositions of acylated insulin analogs with zinc and not acylated naturally occurring insulins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1600~~
AU 1631